K050668

510(k) Summary

FEB 3 2006

(as required per 21CFR; §807.92)

GRT LITE Model PRO-8A Light Therapy System

I. Applicant ..... GRT Solutions, Inc.
425 Gardner St
Los Angeles, CA 90036
Phone: 323-653-2818
Fax: 323-653-2298

II. Contact Name: ..... Dr. George Gonzalez; President
mydoctorgeorge@hotmail.com

III. Device Name

Proprietary Name ..... GRT LITE Model PRO-8A

Common/Usual Name(s) ..... Light Therapy System
Therapeutic Light System

Classification Name ..... Infrared Lamp; (21CFR; §890.5500)

Regulatory Class ..... Class II

Product Code ..... NHN

Establishment Registration Number 9070001

IV. Predicate Device/Substantial Equivalency

The GRT LITE Model PRO-8A is substantially equivalent to other pulsed therapeutic light therapy systems currently in commercial distribution. The Model PRO-8A has the same intended use and similar technological characteristics to predicate devices. It combines the clinically accepted therapeutic uses of several previously FDA 510(k) approved light therapy systems currently in commercial distribution into one compact system.

The technological equivalence to the predicate devices is substantiated by the wavelength and power output generated by the Model PRO-8A. The Model PRO-8A will provide the same treatment benefits and regimens for clinical presentations already approved by the Food and Drug Administration for the predicate devices.

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The predicate devices the Model PRO-8A establishes equivalence to include:

Predicate Device	510(k) #	Manufacturer
Tuco Erchonia PL3000	K012580	Tuco Innovations
Excalibur System	K041530	Stargate International, Inc.
Microlight 830 Laser	K010175	Microlight Corporation of America
Acculaser Pro LLLT Device	K020657	Acculaser, Inc.

V. Intended Use of the Device

The GRT LITE Model PRO-8A is a non-heating lamp, infrared as described under the provisions of 21 CFR §890.5500 and is clinically indicated for:

-- Adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

-- Adjunctive use in providing temporary relief of minor chronic pain associated with Carpal Tunnel Syndrome (CTS).

As with the predicate devices, pain therapy treatment can be prescribed for pain associated with the clinical presentations specified above by having the beams pulsed or continuous with time considerations. The GRT LITE Model PRO-8A's variables conform to the performance specifications of the clinical parameters used by the predicate devices in wavelength, frequency as a function of time, and power output.

VI. Description of the Device

The Model PRO-8A is a hand-held, non-invasive, pain therapy system which utilizes four non-heating light emitting diodes (LED) consisting of two visible LED's and two infrared LED's in one system. It combines the clinically accepted therapeutic treatment of numerous predicate light therapy systems currently in commercial distribution and 510(k) approved.

The system consists of a basic hand-held, battery operated, control unit with the four LED's emitting light through a special red acrylic lens which does not absorb any light transmission. The visible LEDs operate at a measured wavelength of 628nm (±5%) and the infrared LEDs operate at a measured wavelength of 850nm (±5%). The Model PRO-8A complies with all performance, labeling, and manufacturing standards set forth in 21CFR.

VII. Summary of Technical Characteristics of the Device To Referenced Predicate Devices

The GRT LITE Model PRO-8A and the aforementioned predicate devices emit visible and invisible photonic energy to human tissue. The comparing of the technologies is dependent on the laws of physics in that the variables are frequency, wavelength, power output, and time.

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The performance parameters and intended use of the GRT LITE Model PRO-8A are identical to all predicate devices and conforms with all FDA approved application protocols for the devices.

VIII. System Testing

The testing of the Model PRO-8A includes functional performance, electrical safety, and component specification verification. This includes an eight-stage manufacturing testing and verification GRT Solutions, Inc. procedure protocol that is tracked by run component and system serial number.

The operation of the Model PRO-8A is controlled using proprietary PROM technology. Once the CPU is programmed, the "hard software" cannot be changed and/or altered. This hard software affords the operator six different selection options for the Model PRO-8A operating modes. Each of the six operating modes have specific operating frequencies (pulsed or continuous), and visible and infrared light combinations of LED operation. One visible LED is always on, regardless of mode selection, indicating power to the system is on. Every system is checked and tracked, by serial number, for correct diode performance, all six mode operation parameters as they relate to the specific diode, power output, and total operating time.

The Model PRO-8A Light Therapy System is manufactured, performs, is labeled, and is tested to comply with the following standards:

- 21CFR - Subchapter J - Part 1010
- FCC Standard - 47CFR Part 15B
- All Electrical Components Utilized Are UL® Approved

IX. Conclusions

In accordance with testing and comparison to the predicate devices, and pursuant to 21CFR; §890.500, the GRT LITE Model PRO-8A Light Therapy System has the same intended use, with similar functional and performance characteristics.

The device meets or exceeds the design, testing, and labeling standards required by law. The GRT LITE Model PRO-8A Light Therapy System is manufactured and performs as intended and does not raise any new regulatory, safety, and/or clinical efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

Dr. George Gonzalez
President
GRT Solutions, Inc.
425 Gardner Street
Los Angeles, California 90036

Re: K050668
Trade/Device Name: GRT LITE Model PRO-8A
Regulation Number: 21 CFR 890.5500
Regulation Name: Lamp, non-heating for adjunctive use in pain therapy
Regulatory Class: II
Product Code: NHN
Dated: December 19, 2005
Received: December 20, 2005

Dear Dr. Gonzalez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melk MD for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K050668

Device Name: GRT LITE Model PRO-8A Light Therapy System

Indications For Use: The GRT Model PRO-8A is a non-heating lamp, infrared as described under the provisions of 21 CFR §890.5500 and its indications for use:

- Adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

- Adjunctive use in providing temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome (CTS).

Prescription Use: X **AND/OR** **Over The Counter Use:** _____
(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brickman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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